

## REMARKS

All pending claims have been canceled without prejudice or disclaimer. Claims 52-63 have been added and therefore are pending in the present application. Claims 52-63 are supported throughout the specification, including the original claims.

The specification has been amended to delete embedded hyperlinks at pages 12 and 14; and to correct typographical errors at page 23.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### **I. The Rejection of Claims 41 and 47 under 35 U.S.C. 112**

Claims 41 and 47 are rejected under 35 U.S.C. 112 as being indefinite. Specifically, the Office objected to the recitation "derived from". Claims 41 and 47 have been canceled without prejudice or disclaimer. Furthermore, the newly presented claims do not recite the term "derived from". Applicants therefore submit that this rejection is rendered moot.

### **II. The Rejection of Claims 35-49 and 51 under 35 U.S.C. 112**

Claims 35-49 and 51 are rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. Specifically, the Office states that "The claims are drawn to a method of producing a genus of fermentation products having unknown structure by using a glucoamylase. There is insufficient descriptive support for the genus of these fermentation products." This rejection is respectfully traversed.

Under 35 U.S.C. § 112, "[t]he specification shall contain a written description of the invention...." The purpose of the written description requirement is to "insure[ ] that subject matter presented in the form of a claim subsequent to the filing date of the application was sufficiently disclosed at the time of filing so that the prima facie date of invention can fairly be held to be the filing date of the application." *In re Smith and Hubin*, 178 U.S.P.Q. 620, 623 (C.C.P.A. 1973).

It is well settled that "[t]he test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter ..." *In re Kaslow*, 217 USPQ 1089, 1096 (Fed. Cir. 1983). The written description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See *In re Marzocchi*, 169 U.S.P.Q. 367 (C.C.P.A. 1971).

Moreover, an original claim or a claim of similar scope complies with the written description requirement.

Where the claim is an original claim, the underlying concept of insuring disclosure as of the filing date is satisfied, and the description requirement has likewise been held to be satisfied. See *In re Gardner*, 177 U.S.P.Q. 396, note 1, supplemental opinion, 178 U.S.P.Q. 149 (C.C.P.A. 1973); *In re DiLeone*, 168 U.S.P.Q. 592 (1971).

*In re Smith and Hubin, supra*, 178 U.S.P.Q. at 624. See also *In re Koller*, 204 U.S.P.Q. 702, 706 (C.C.P.A. 1980) ("[O]riginal claims constitute their own description. Later added claims of similar scope and wording are described thereby").

Moreover, it is well established that "[i]t is not necessary that the claimed subject matter be described in *ipsis verbis* to satisfy the written description requirement...." *Fields v. Conover*, 170 U.S.P.Q. 276 (C.C.P.A. 1971) and *In re Lukach*, 169 U.S.P.Q. 795 (C.C.P.A. 1971). Nor does the statute require a specific example. The issue is whether the ... specification conveys clearly to those skilled in the art that [the inventor] invented the [claimed subject matter]." *Heymes v. Takaya*, 6 U.S.P.Q.2d 1448, 1452, on request for consideration, 6 U.S.P.Q.2d 2055 (P.T.O. Bd. Pat. App. & Int'f 1988).

Applicants respectfully submit that the claims of the instant application comply with the written description requirement under 35 U.S.C. 112, first paragraph.

The claimed invention is directed to a process for producing a fermentation product, comprising: (a) saccharifying a milled starch-containing material with a glucoamylase with at least 98% sequence identity with the sequence of amino acids 1-561 of SEQ ID NO: 2 and an acid alpha-amylase hybrid comprising an *Aspergillus niger* acid alpha-amylase catalytic domain and a CBM from an *Aspergillus kawachii* alpha-amylase, at a temperature below the initial gelatinization temperature of the starch-containing material, and (b) fermenting using a fermenting organism, wherein the saccharification and fermentation are carried out simultaneously and the temperature during the saccharification and fermentation is between 28°C and 36°C.

The specification describes numerous fermentation products which could be produced by the claimed process. For example, the specification discloses at page 6, lines 19-33 that the fermentation product may be an alcohol, organic acid, ketone, antibiotic, enzyme, vitamin or hormone. Other fermentation products are well known in the art.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

### **III. The Rejection of Claims 35-49 and 51 under 35 U.S.C. 112**

Claims 35-49 and 51 are rejected under 35 U.S.C. 112 for failing to comply with the enablement requirement. This rejection is respectfully traversed.

It is well settled that "[t]he first paragraph of section 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance." *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). Moreover, "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 169 U.S.P.Q. at 369.

"The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art ... The test is not quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed ..." *Ex parte Jackson*, 217 U.S.P.Q. 804 (Bd. Pat. App. 1982).

It is also well settled that an assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974). See also *U.S. v. Telectronics*, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974); *Ex parte Hitzeman*, 9 U.S.P.Q.2d 1821 (BPAI 1988).

Moreover, in the absence of any evidence or apparent reason why compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. *In re Kamal*, 158 U.S.P.Q. 320 (C.C.P.A. 1968). See also *In re Stark*, 172 U.S.P.Q. 402, 406 n. 4 (C.C.P.A. 1972) (the burden is upon the Patent Office to set forth reasonable grounds in support of its contention that a claim reads on inoperable subject matter).

Applicants respectfully submit that the claims of the instant application comply with the written description requirement under 35 U.S.C. 112, first paragraph.

The claimed invention is directed to a process for producing a fermentation product, comprising: (a) saccharifying a milled starch-containing material with a glucoamylase with at

least 98% sequence identity with the sequence of amino acids 1-561 of SEQ ID NO: 2 and an acid alpha-amylase hybrid comprising an *Aspergillus niger* acid alpha-amylase catalytic domain and a CBM from an *Aspergillus kawachii* alpha-amylase, at a temperature below the initial gelatinization temperature of the starch-containing material, and (b) fermenting using a fermenting organism, wherein the saccharification and fermentation are carried out simultaneously and the temperature during the saccharification and fermentation is between 28°C and 36°C.

The specification describes numerous fermentation products which could be produced by the claimed process. For example, the specification discloses at page 6, lines 19-33 that the fermentation product may be an alcohol, organic acid, ketone, antibiotic, enzyme, vitamin or hormone. Other fermentation products are well known in the art.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **IV. The Rejection of Claims 35-40, 42-44 and 50-51 under 35 U.S.C. 102**

Claims 35-40, 42-44 and 50-51 are rejected under 35 U.S.C. 102 as being anticipated by Nagasaka et al. (*Appl. Microbiol. Biotechnol.* 50: 323-330 (1998)). This rejection is respectfully traversed.

Nagasaka et al. disclose saccharification of raw starch with a *Corticium rolfsii* glucoamylase.

However, Nagasaka et al. do not disclose saccharification of raw starch with a glucoamylase with at least 98% sequence identity with the sequence of amino acids 1-561 of SEQ ID NO: 2 and an acid alpha-amylase hybrid comprising an *Aspergillus niger* acid alpha-amylase catalytic domain and a CBM from an *Aspergillus kawachii* alpha-amylase.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **V. The Rejection of Claims 35-40, 42, 44-47 and 49-51 under 35 U.S.C. 102**

Claims 35-40, 42, 44-47 and 49-51 are rejected under 35 U.S.C. 102 as being anticipated by Borchert et al. (U.S. Patent Nos. 7,129,069 and 7,312,055). This rejection is respectfully traversed.

Borchert et al. disclose hybrid enzymes comprising a glucoamylase catalytic domain and a carbohydrate binding module.

However, Borchert et al. do not disclose saccharification of raw starch with a glucoamylase with at least 98% sequence identity with the sequence of amino acids 1-561 of SEQ ID NO: 2 and an acid alpha-amylase hybrid comprising an *Aspergillus niger* acid alpha-amylase catalytic domain and a CBM from an *Aspergillus kawachii* alpha-amylase.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejection.

## **VI. The Rejection of Claims 35-40 and 42-51 under 35 U.S.C. 103**

Claims 35-40 and 42-51 are rejected under 35 U.S.C. 103 as being unpatentable over Veit et al. (U.S. Patent No. 7,244,597 or WO 02/38787) and Nagasaka et al. (*Appl. Microbiol. Biotechnol.* 50: 323-330 (1998)). This rejection is respectfully traversed.

Veit et al. disclose a process of producing ethanol comprising primary and secondary liquefaction steps, wherein the primary liquefaction is performed at a temperature of 60-95°C and the secondary liquefaction step is performed at a temperature of 95-140°C to further gelatinize the starch.

However, Veit et al. do not teach or suggest a process of producing ethanol, comprising saccharification of raw starch.

As explained above, Nagasaka et al. do not teach or suggest saccharification of raw starch with a glucoamylase with at least 98% sequence identity with the sequence of amino acids 1-561 of SEQ ID NO: 2 and an acid alpha-amylase hybrid comprising an *Aspergillus niger* acid alpha-amylase catalytic domain and a CBM from an *Aspergillus kawachii* alpha-amylase.

Moreover, Example 2 of the instant application describes saccharification of milled corn with the following enzyme compositions:

1. *Athelia rolfsii* glucoamylase comprising the sequence of amino acids 1-561 of SEQ ID NO: 2;
2. *Athelia rolfsii* glucoamylase comprising the sequence of amino acids 1-561 of SEQ ID NO: 2 and an acid alpha-amylase hybrid comprising *Aspergillus niger* acid alpha-amylase catalytic domain with *Aspergillus kawachii* alpha-amylase linker and CBM;
3. *Aspergillus niger* glucoamylase; and
4. *Aspergillus niger* glucoamylase and an acid alpha-amylase hybrid comprising *Aspergillus niger* acid alpha-amylase catalytic domain with *Aspergillus kawachii* alpha-amylase linker and CBM.

The glucose concentrations obtained in the saccharification are shown below:

Treatment	4 hour Glucose (g/L)
0.263 mg/g DS <i>Aspergillus niger</i> glucoamylase	33.2
0.263 mg/g DS <i>Aspergillus niger</i> glucoamylase + 0.034 mg/g DS <i>Aspergillus niger</i> acid alpha-amylase with <i>Aspergillus kawachii</i> alpha-amylase linker and CBM	40.4
0.263 mg/g DS <i>Athelia rolfsii</i> glucoamylase	45.6
0.263 mg/g DS <i>Athelia rolfsii</i> glucoamylase + 0.034 mg/g DS <i>Aspergillus niger</i> acid alpha-amylase with <i>Aspergillus kawachii</i> alpha-amylase linker and CBM	63.2

As shown in the table, the addition of the acid alpha-amylase hybrid comprising *Aspergillus niger* acid alpha-amylase catalytic domain with *Aspergillus kawachii* alpha-amylase linker and CBM to *Aspergillus niger* glucoamylase resulted in an increase of the glucose concentration from 33.2 to 40.4 g/l, or about 21.7%  $((40.4 - 33.2)/33.2)$ , whereas the addition of the acid alpha-amylase hybrid comprising *Aspergillus niger* acid alpha-amylase catalytic domain with *Aspergillus kawachii* alpha-amylase linker and CBM to the *Aspergillus niger* glucoamylase resulted in an increase of the glucose concentration from 45.6 to 63.2 g/l, or about 38.6%  $((63.2 - 45.6)/45.6)$ , a significantly greater increase. Since these results are not predicted by the prior art, they are surprising and unexpected.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **VII. The Rejection of Claims 35-40, 42, 47 and 49-51 under the Doctrine of Obviousness-Type Double Patenting**

Claims 35-40, 42, 47 and 49-51 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,129,069 and U.S. Patent No. 7,312,055. This rejection is respectfully traversed.

Claims 1-10 of U.S. Patent No. 7,129,069 and U.S. Patent No. 7,312,055 are directed to enzyme hybrids comprising a glucoamylase catalytic domain and a carbohydrate binding module.

However, claims 1-10 of U.S. Patent No. 7,129,069 and U.S. Patent No. 7,312,055 do not teach or suggest saccharification of raw starch with a glucoamylase with at least 98% sequence

identity with the sequence of amino acids 1-561 of SEQ ID NO: 2 and an acid alpha-amylase hybrid comprising an *Aspergillus niger* acid alpha-amylase catalytic domain and a CBM from an *Aspergillus kawachii* alpha-amylase.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under the doctrine of obviousness-type double patenting. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **VIII. Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

All required fees were charged to Novozymes North America, Inc.'s Deposit Account No. 50-1701 at the time of electronic filing. The USPTO is authorized to charge this Deposit Account should any additional fees be due.

Respectfully submitted,

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